MEETINGS AND NETWORKS FOR METHODOLOGICAL DEVELOPMENT IN INTERDISCIPLINARY RESEARCH

RELEASE DATE: January 23, 2004

RFA NUMBER: RFA-RM-04-014

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:
National Institutes of Health (NIH)
(http://www.nih.gov)

This RFA is developed as an NIH Roadmap initiative (http://nihroadmap.nih.gov/). All NIH Institutes and Centers participate in Roadmap initiatives. This RFA will be administered by the National Cancer Institute on behalf of the NIH.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.394, 93.395, 93.396

LETTER OF INTENT RECEIPT DATE: March 26, 2004
APPLICATION RECEIPT DATE: April 26, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS RFA

The Institutes, Centers, and Offices of the National Institutes of Health (NIH) invite applications for meetings or networks to develop methodologies that will facilitate interdisciplinary health research among behavioral or social scientists and investigators in the biomedical, mathematical/computational, physical sciences and/or engineering. The purpose of this RFA is to stimulate the development of methods and measures in the behavioral or social sciences in order to more fully integrate the scientific approaches and advances in these disciplines into interdisciplinary research designed to solve complex health problems. NIH is especially interested in applications that identify a topic in human health/well-being research that can be significantly advanced by using an interdisciplinary approach bringing together a new combination of disciplines and by developing innovative, interdisciplinary approaches and methods.

PROGRAM OBJECTIVES

The National Institutes of Health (NIH) are engaged in a series of activities collectively known as the "NIH Roadmap." The Roadmap's goal, in keeping with the NIH mission of uncovering new knowledge about the prevention, detection, diagnosis, and treatment of disease and disability, is to accelerate both the pace of discovery in these key areas and the translation of therapies from bench to bedside. In the course of developing the NIH Roadmap, it has become clear that scientific advances are increasingly being made at the interfaces of traditional disciplines, and that approaches to science are becoming more integrative. These advances require cooperative efforts, typically in the form of investigators from diverse research backgrounds working collectively across traditional disciplinary boundaries to answer scientific questions and achieve specific endpoints. The development of methods, measurements, and technologies capable of crossing disciplinary boundaries and contributing to integrative and team approaches to understanding complex health problems is also required. Interdisciplinary technology and methods innovations have therefore emerged as one of the major themes in Roadmap implementation. (Additional information about the NIH Roadmap can be at http://nihroadmap.nih.gov/index.asp.)

An interdisciplinary approach is distinguished from a multidisciplinary approach in that a multidisciplinary approach brings experts from diverse disciplines to address collectively a common complex problem, each from his or her unique perspective. By contrast, an interdisciplinary approach results from the melding of two or more disciplines to create a new (interdisciplinary) science. Biophysics, biostatistics, bioinformatics, bioengineering, social neuroscience, biodemography, behavioral economics, and sychoneuroimmunology are just some examples of existing interdisciplinary sciences. NIH recognizes the value and enormous contributions that existing interdisciplinary approaches have made and are making to our understanding of health, disease, and disability.

It has become increasingly apparent that the behavioral and social sciences have broad significance and are fundamental to the comprehensive understanding of disease etiology and treatment as well as to the promotion of health and well being. Behavioral and social factors have significant impacts across the lifespan on diseases ranging from cardiovascular disease, to cancer, to diabetes, and to oral and mental health. Innovations in behavioral and social science methods and technologies have not kept pace with those in the biomedical sciences, and the analytic strategies necessary for the integration of the behavioral and social sciences with biomedical, computational, physical and engineering sciences have not yet been articulated. The exploration and development of new interdisciplinary topics, methodological approaches, and combinations of the research capabilities of disparate disciplines are needed to support the development of interdisciplinary research that includes the behavioral and social sciences.

SPECIFIC OBJECTIVES

This RFA will support, over a 1- or 2-year period, scientific meetings or networks to explore and/or develop innovative methodologies or technologies in the behavioral or social sciences, with the ultimate goal of better integrating these disciplines into interdisciplinary health research. Applications are required to focus on a specific research topic related to human health or well-being and to include participation by investigators from a minimum of two disciplines, at least one of which is a behavioral or social science. We strongly encourage inclusion of more than two disciplines and of biomedical, mathematical/computational, physical sciences and/or engineering, to maximize methodological development at the intersections of these fields and the behavioral and social sciences. A definition of behavioral and social sciences research for the NIH can be found at http://obssr.od.nih.gov/funding/definition.html.

In recognition of the fact that interdisciplinary projects may be in different stages of development, this RFA will support scientific meetings or networks. A scientific meeting is defined as a gathering, symposium, seminar, conference, workshop or any other organized, formal meeting where persons assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge. A network is defined as a group of investigators interacting or communicating to explore the potential of research collaborations. In all cases, applicants are encouraged to consider adopting innovative mechanisms (e.g., web-based networks, webcasts, new communicative media) as primary or supplementary platforms for network or conference communications and interactions.

The aim of a research network is to foster initial development of collaborative work; accordingly, investigators need not demonstrate any history of prior collaboration. However, those factors in the investigators' background and/or institutional circumstances that would facilitate success in collaboration should be clearly delineated. Networks should provide a clear plan for developing the collaboration. Such efforts could include travel among sites for informal meetings; workshops and small conferences; consultants; and analyses of extant data sets, using new methodologies or

approaches. The purpose of these activities will be to refine conceptual frameworks for methodological development and to identify which specific research questions show the greatest promise for scientific advancement. Networks should comprise at least three investigators. The network's proposed activities may also include pilot studies to demonstrate feasibility of the methodologies or technologies to be developed. The proposal of pilot studies is not a requirement for applications: depending on the breadth of disciplines involved and the current knowledge about the chosen research topic, it is expected that some networks will be ready for pilot research later than others.

NIH recognizes that multidisciplinary approaches may be a necessary step in the evolution of interdisciplinary research. Thus, for the purposes of this RFA, it is acceptable for applications to propose meetings or networks in multidisciplinary approaches as a precursor to interdisciplinary research, and to propose activities that facilitate communication among different disciplines or that promote but do not necessarily completely achieve integration of different disciplines in the proposed project period.

The proposed scientific meetings or networks should address, in the context of a specific, health-related topic, at least one of four general methodological issue areas: research design, data collection techniques, measurement, or analytic methods.

1. Research Design: Research design determines how well a research plan can test hypotheses and achieve specific aims. Research design encompasses many decisions including the following: sampling plan; selection of appropriate study designs, methods, procedures and measures; and assuring confidence in the study's internal and external validity. Research design issues also include new approaches to the conduct of the research, such as intergenerational approaches to study a health topic, or the use of a variety of assessment approaches (e.g., ethnography, focus groups, standardized questionnaires, semi-structured interviews) to investigate a health topic in an interdisciplinary fashion.

2. Measurement: The development and validation of research measures are vitally important for improving the collection of valid and reliable data and have implications for the inferences or conclusions that will be drawn from the data. For research efforts that rely on self-report, data collection instruments and questions must be appropriate for the particular group (as defined by age, gender, culture, or other relevant characteristics) in which they will be used. Objective measures of individual or group behaviors or of the physical or social environment should also be assessed for appropriateness and relevance. For particular research questions, combinations of self-report and objective measures may prove optimal, e.g., objective assessment of an individual's behavior with collection of the subject's own report of social context at the time the behavior occurs.

3. Data Collection Techniques: Data collection techniques are the tools and procedures scientists use for implementing research designs and obtaining measurements. Methods for collecting research data have an important impact on data validity and reliability. For example, studies have suggested that use of self-administered instruments can facilitate

the reporting of sensitive or illegal behaviors. Innovative methodologies can also lead to the collection of new or more complex types of data by behavioral scientists. Recent developments in computer-assisted interviewing have permitted more complex question sequences in survey research, and the development of small computers with instant data entry of self-report and/or objective information has permitted the collection of time-specific data on a variety of behaviors and outcomes (e.g., cigarette smoking, physical activity, and pain). In addition, implicit measures have allowed researchers to examine processes of which people themselves have been unaware. Continued improvement and innovation in data collection methods are important for many types of research, including clinical interviews, observational studies, participatory action research, community research and surveys. New methods for qualitative research are also needed, as are techniques that facilitate the integration and validation of qualitative and quantitative measurement.

4. Analytic Methods: Analytic methods encompass the concepts and techniques used in analyzing data and interpreting and reporting results. The goal of new and improved analytic methods is to improve estimation, hypothesis testing, and causal modeling based on scientific data. Challenges include developing techniques that distinguish underlying regularities from the noise created by variability and imprecise measurement; developing causal inferences from quasi-experimental or non-experimental data; improving both the internal validity and external validity (generalizability) of measures and studies; and developing appropriate analytic techniques for the integration of behavioral and social science data with those of other disciplines, including the biomedical, computational and/or physical sciences and engineering.

Examples of scientific meetings or networks for methodological development in interdisciplinary research might include, but are not limited to, the following:

o Gatherings of clinicians, behavioral science researchers, information technology specialists, psychometricians, regulators, and patient advocates to discuss how computer-based technology influences both patient-provider communication and decision-making and researcher knowledge;

o A network of physiologists, behavioral scientists, social scientists and clinicians to develop methodologies for the collection and analysis of biological and behavioral measures of an individual's allostatic load (i.e., the physiological price the body pays for having to adapt to various psychosocial, physical, and environmental challenges), which may influence a patient's response to clinical care;

o A network of exercise scientists, engineers, cognitive scientists and social psychologists to develop methods for the simultaneous collection of objective measures of bodily movement and self-report of the social context and motivational variables that might influence an individual's performance of physical activity;

o A meeting of cognitive neuroscientists, psychologists, statisticians, psychometricians, and engineers to discuss development of experimental designs and methodologies that

will allow for the collection of more sophisticated cognitive, emotional, social, and biological data during brain imaging studies than are currently possible;

o A meeting of geneticists, behavioral researchers, and statisticians to develop methods for the analysis of gene-social environment interactions that influence physiological variables and health;

o A network of gerontologists, epidemiologists, economists, and cognitive neuroscientists to develop epidemiological surveys of the elderly that would include measures of age-related changes in brain function and cognition and the impact of changing cognition on decision-making in the areas of health and finances;

o A network of demographers, ecologists, biologists, and geographic information systems experts to develop methods of examining how population processes and health interact with changes in the natural environment;

o A network of statisticians, econometricians, demographers, and health care providers and/or psychologists to develop methods of dealing with biases in clinical trials (including both medical and behavioral interventions) that result from enrollees not being representative of the overall target population;

o A network of health care providers, social workers, and statisticians to develop methods of assessing the effectiveness of health interventions for children and the factors affecting that effectiveness;

o A network of nutritionists, epidemiologists, psychometricians, psychologists, geneticists, engineers, and clinicians to refine current approaches and develop innovative methods to understand dietary/nutritional patterns and their relation to health outcomes;

o A meeting of anthropologists, sociologists, computer scientists, cognitive neuroscientists, and health researchers to discuss the meaning, validity, and improvement of health information gathered by serial time-intensive assessments via innovative technology for different segments of the population (e.g., older adults, ethnic minorities, children); and

o A network of family researchers, demographers, gerontologists, pediatricians, psychologists, clinicians, and epidemiologists that would begin to develop surveys or research instruments to assess health states and family functioning from both life-span and systems perspectives.

Reference Reports:

In June, 2000 the NIH Office of Behavioral and Social Sciences Research (OBSSR) held a conference "Toward Higher Levels of Analysis: Progress and Promise in Research on Social and Cultural Dimensions of Health." In an agenda-setting activity that followed the conference, a panel of scientists developed an ambitious research agenda on the social

and cultural dimensions of health that included detailed recommendations relating to needed methodological development in this area. Potential applicants are encouraged to consult this report, available at http://obssr.od.nih.gov/Conf_Wkshp/higherlevel/conference.html.

In September 2001, NIH sponsored an International Conference entitled "Stigma and Global Health: Developing a Research Agenda." Among the recommendations was one to encourage research intended to develop methodological, evaluative, and analytic tools for 1) studying stigma and its consequences with respect to health and 2) development, evaluation, and optimization of interventions to prevent or mitigate the negative effects of stigma and discrimination on health. In both areas, it was recommended that the social and cultural dimensions of stigma and its manifestations be included. Applicants are encouraged to refer to the stigma conference website at www.stigmaconference.nih.gov for further resources and information.

In addition, the following reports may be useful as general references on behavior and social sciences research as it relates to health:

New Horizons in Health: An Integrative Approach. (2001). B.H. Singer and C.D. Ryff, Editors, Committee on Future Directions for Behavioral and Social Sciences Research at the National Institutes of Health, Board on Behavioral, Cognitive, and Sensory Sciences, National Research Council (http://www.nap.edu/catalog/10002.html).

Health and Behavior: The Interplay of Biological, Behavioral, and Societal Influences (2001). Committee on Health and Behavior: Research, Practice and Policy, Board on Neuroscience and Behavioral Health, Institute of Medicine (http://books.nap.edu/catalog/9838.html).

Cells and Surveys: Should Biological Measures be Included in Social Science Research? (2001) C.E. Finch, J.W. Vaupel, and K. Kinsella, Editors, Committee on Population, Commission on Behavioral and Social Sciences and Education, National Research Council (http://www.nap.edu/books/0309071992/html/).

From Neurons to Neighborhoods: The Science of Early Childhood Development (2000). J.P. Shonkoff and D.A. Phillips, Editors; Committee on Integrating the Science of Early Childhood Development, Board on Children, Youth, and Families, National Research Council (http://books.nap.edu/catalog/9824.html).

Bridging Disciplines in the Brain, Behavioral, and Clinical Sciences (2000). T.C. Pellmar and L. Eisenberg, Editors; Committee on Building Bridges in the Brain, Behavioral, and Clinical Sciences; Division of Neuroscience and Behavioral Health, Institute of Medicine (http://books.nap.edu/catalog/9942.html).

Expanding the Boundaries of Health and Social Science: Case Studies in Interdisciplinary Innovation (2003). F. Kessel, P.Rosenfield and N. Anderson, Editors; New York: Oxford University Press.

Rebuilding the Unity of Health and the Environment (2001). K. Hanna and C. Coussens, Editors; Roundtable on Environmental Health Sciences, Research, and Medicine, Division of Health Sciences Policy, Institute of Medicine (http://www.nap.edu/books/030907259X/html/).

MECHANISMS OF SUPPORT

This RFA will use the R13 Support for Conferences and Scientific Meetings and for networks, the R21 Exploratory/Developmental Research Grant Award. An applicant or group of applicants may submit an application for the R13 or R21 award, but not for both mechanisms. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. The anticipated award date is September 30, 2004. This RFA may be re-issued at a later date. Future unsolicited, competing-continuation applications based on this project will compete with all investigator-initiated applications and will be reviewed according to the customary peer review procedures.

This RFA is distinct from PAR 03-176, "NIH Support for Conferences and Scientific Meetings," which was issued by NIH in September, 2003 (http://grants.nih.gov/grants/guide/pa-files/PAR-03-176.html), and which also uses the R13 award mechanism. This RFA has different requirements, budgetary limits, and application instructions. In addition, this RFA DOES NOT require that applications for an R13 award present a letter from the appropriate NIH Institute/Center (IC) staff documenting advance permission to submit an R13 application.

This RFA is distinct from PA 03-017, "NIH Exploratory/Developmental Research Grant Award" (http://grants.nih.gov/grants/guide/pa-files/PA-03-107.html), which was issued in April, 2003, and which describes the use of the R21 award mechanism for investigator-initiated applications. Again, the requirements, budgetary limitations and applications of this RFA differ from those stipulated in PA 03-017.

For R21s: This RFA uses just-in-time concepts. It also uses the modular budgeting format (see http://grants.nih.gov/grants/funding/modular/modular.htm). Since the direct costs of the meetings and networks will always be less than $250,000 yearly, the modular budget format is required. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm.

For R13s: This RFA does not use just-in-time concepts and does not use modular budgeting formats. Follow the instructions in the PHS 398 http://grants.nih.gov/grants/funding/phs398/phs398.html for non-modular research grant applications.

FUNDS AVAILABLE

The NIH intends to commit approximately $400,000 in FY 2004 to fund three to five new and/or competitive continuation grants in response to this RFA. Support will be offered for a maximum of two years. Requests for R13 awards may not exceed $40,000 total costs per year. Facilities and administrative (F&A) costs are not allowed for the R13 mechanism. For R21 awards (networks), requests may not exceed $150,000 total direct costs for the entire term of support (2 years maximum), with F&A costs paid at the grantee institution's negotiated rate. Because the nature and scope of the proposed meetings/networks will vary from application to application, it is anticipated that the size and duration of each award will also vary. Awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

o For-profit or non-profit organizations;
o Public or private institutions, such as universities, colleges, hospitals, and laboratories;
o Units of State and local governments;
o Eligible agencies of the Federal government;
o Domestic or foreign institutions/organizations for R21 awards; and
o Domestic institutions/organizations for R13 awards (only domestic institutions or organizations, including established scientific or professional societies, are eligible to apply for R13 support)-- Both domestic and international meetings may be supported; however, an international meeting can be supported only through the U.S. representative organization of an established international scientific or professional society.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

o For 2-year awards, the progress report (Form PHS 2590, available at http://grants.nih.gov/grants/funding/2590/2590.htm) must be submitted 2 months prior to the next budget period start date. It should include a report on the previous gathering supported by the current grant, as well as a full description of the next planned meeting(s).

o A critical part of the application for NIH support of scientific meetings and networks is documentation of appropriate representation of women, racial/ethnic minorities, persons with disabilities, and other individuals who have been traditionally underrepresented in science. These individuals must be included in all aspects of planning, organization and implementation of NIH-sponsored and/or supported meetings. "Appropriate representation" means representation based on the availability of scientists from these groups known to be working in a particular field of biomedical or behavioral research. If appropriate representation is not apparent, no award will be issued until program staff are assured of concerted recruitment efforts. Organizers of scientific meetings must document compliance with the GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN SCIENTIFIC MEETINGS SUPPORTED BY THE NIH (included at http://grants.nih.gov/grants/funding/r13/index.htm).

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Deborah H. Olster, Ph.D.
Office of Behavioral and Social Sciences Research
National Institutes of Health
One Center Drive, Room 256
Bethesda, MD 20892-1146
Telephone: (301) 451-4286
Fax: (301) 402-1150
E-mail: olsterd@od.nih.gov

Audie A. Atienza, Ph.D.
Division of Cancer Control and Population Sciences
National Cancer Institute
6130 Executive Blvd., EPN 4074A
Bethesda, MD 20892-7335
Telephone: (301) 402-8426
Fax: (301) 480-2087
E-mail: atienzaa@mail.nih.gov

o Direct your questions about peer review issues to:

Referral Officer
National Cancer Institute
Division of Extramural Activities
6116 Executive Boulevard, Room 8041, MSC 8329

Bethesda, MD 20892-8329
Rockville, MD 20852 (for express/courier service)
Telephone: (301) 496-3428
FAX: (301) 402-0275
Email: ncirefof@dea.nci.nih.gov

o Direct your questions about financial or grants management matters to:

Bill Wells
Grants Administration Branch
National Cancer Institute
6120 Executive Blvd., EPS Room 243
Bethesda, MD 20892
Rockville, MD 20852 (for express/courier service)
Telephone: 301-496-8634
E-Mail: wellsw@mail.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other Key Personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by March 26, 2004. The letter of intent should be sent to:

Audie A. Atienza, Ph.D.
Division of Cancer Control and Population Sciences
National Cancer Institute
6130 Executive Blvd., EPN 4074A
Bethesda, MD 20892-7335
Telephone: (301) 402-8426
Fax: (301) 480-2087
E-mail: atienzaa@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at http://www.dunandbradstreet.com/. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SUPPLEMENTARY INSTRUCTIONS

The following instructions are to be used in conjunction with the Instructions accompanying application form PHS 398 (rev. 05/2001):

o Form Page 2 (Description, Performance Site(s)& Key Personnel). Complete a very brief description of the proposed meeting or networks, including the dates, location, types of participants, goals, and topics to be covered. Enter the site of the meeting as the Performance Site. For R13 awards, Key Personnel are defined as the Principal Investigator and those individuals responsible for the scientific planning, and organization of the meeting. For R21 awards, Key Personnel are defined as the Principal Investigator and additional network participants.

o The budget justification should include a justification for each proposed personnel position, including role and proposed level of effort. Although funding from other sources to support these projects is not required, include information regarding efforts to obtain funding for this meeting/network from other sources, if such efforts are anticipated, ongoing or complete.

Allowable Costs: Salaries in proportion to the time or effort spent directly on the meeting or network; rental of necessary equipment; travel and per diem or subsistence allowances; supplies needed for conduct of the meeting or network, only if received for use during the budget period; conference services; publication costs; registration fees; speakers' fees.

Non-allowable Costs: Purchase of equipment; transportation costs exceeding coach class fares; visas; passports; entertainment; tips; bar charges; personal telephone calls; laundry charges; organization dues; honoraria or other payments for the purpose of conferring distinction or communicating respect, esteem or admiration; patient care; alterations or renovations.

o Form Page 6 (Biographical Sketch). Complete for Principal Investigator, Key Personnel, and for R13 awards, and any confirmed key speakers.

o Research Plan.

SECTIONS A-D OF THE RESEARCH PLAN MAY NOT EXCEED 15 PAGES.

Use this section of the application to describe the objectives, specific program, and logistical arrangements for the scientific meeting or network. Describe the format and agenda, including the principal topics to be covered, problems to be addressed, and developments or contributions the meeting might stimulate. Provide the names and credentials of key participants in the meeting or network, including the basis for their selection. Letters of agreement from participants should be included in Section I ("Consultants").

Applications requesting two years of support should provide the following additional information for the second year requested, in as much detail as possible: meeting topic(s); tentative dates, locations, and participants; and contingency plans for future gatherings dependent on, for example, the outcome of the first year's meeting or developments in the field.

This section should also include the following:

a. A description of the health or well-being issue that will be the focus of the meeting(s) or network.

b. A description of how the proposed methodological innovation(s) will advance the specific interdisciplinary research goals and objectives in the chosen health topic area.

c. A cogent rationale as to why an interdisciplinary approach is needed to address the chosen health research topic. This discussion should include a compelling justification for the interdisciplinary potential of the research collaboration, including the relevance for clinical or practical utility, the theoretical progress that will be accomplished through multi- or interdisciplinary networking, and the reasons why an interdisciplinary approach will advance the field or answer previously intractable questions. In all cases, a strong knowledge base should already be available that is germane to the interdisciplinary effort.

d. A description of the overall impact the proposed methodology will have on other health or well-being research topics, on the general scientific fields represented by the participants, and on future research efforts to integrate the behavioral and social sciences in interdisciplinary health research.

e. A description of the partnerships among the behavioral or social scientists, scientists of other disciplines, key stakeholders and others with relevant expertise that now exist or that will be developed or nurtured by the proposed meeting(s) or network. Applications must include participation by investigators from a minimum of two disciplines, at least

one of which is a behavioral or social science. We strongly encourage inclusion of more than two disciplines and of biomedical, mathematical/computational physical sciences and/or engineering, to maximize methodological development at the intersections of these fields and the behavioral and social sciences. Networks require a minimum of three investigators. In all cases, applications should be clear about how communication will occur across boundaries; network applications should detail communication plans so that the feasibility of achieving a fully-developed collaborative research partnership is apparent.

f. A description of any planned pre-meeting or follow-up activities (e.g., preparation of conference papers, publications of proceedings) to the meetings or workshops. If applicable, plans for broader dissemination of any materials should be described.

g. Plans for the appropriate involvement of women, minorities, and persons with disabilities in the planning and implementation of the proposed meeting or network. For meetings (R13 awards), estimate the expected size and composition of the audience, as well as the method of selection. Describe plans for publicizing the meeting and publication of proceedings. Identify related meetings held on the subject during the past three years. If this is one of a series of periodic meetings held by a permanent sponsoring organization, briefly describe and evaluate the last meeting in the series.

h. Applications for networks (R21) should present a description of the anticipated longer-term goals of the collaboration as it develops. Such goals might variously include an application for a developmental grant (R03), an R01-based research collaboration, or a larger center mechanism.

o Appendix. The Appendix is limited to announcements and reports of previous meetings under the same sponsorship. Appendix materials should be comprised of single-sided, unbound materials, with separators between documents.

o Checklist. The checklist should be submitted.

For R13 awards, no information regarding Facilities and Administrative (F&A) Costs should be included as this is not an allowable cost for this mechanism. For R21 awards, the applicant institution's negotiated F&A cost rates should be indicated on the Checklist.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications for R21 awards must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at http://grants.nih.gov/grants/funding/modular/modular.htm.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Referral Officer
National Cancer Institute
Division of Extramural Activities
6116 Executive Boulevard, Room 8041, MSC 8329
Bethesda, MD 20892-8329
Rockville, MD 20852
Telephone: (301) 496-3428
FAX: (301) 402-0275
Email: ncirefof@dea.nci.nih.gov

Appendix materials should be comprised of single-sided, unbound materials, with separators between documents.

APPLICATIONS HAND-DELIVERED BY INDIVIDUALS TO THE NATIONAL CANCER INSTITUTE WILL NO LONGER BE ACCEPTED. This policy does not apply to courier deliveries (i.e. FEDEX, UPS, DHL, etc.) (http://grants.nih.gov/grants/guide/notice-files/NOT-CA-02-002.html).
This policy is similar to and consistent with the policy for applications addressed to Centers for Scientific Review as published in the NIH Guide Notice http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-012.html.

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will not be reviewed.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is, the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the National Cancer Institute. Incomplete and/or non-responsive applications will not be reviewed. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the National Cancer Institute in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score;

o Receive a written critique; and

o Receive a second level review by the appropriate National Advisory Council or Board.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

o Significance
o Approach
o Innovation
o Investigator
o Environment

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

SIGNIFICANCE: Does this proposed methodological development address an important health research topic? If the aims of the application are achieved, how will scientific knowledge be advanced, in the chosen as well as in other health research topic areas, in the general scientific fields represented by the participants, and in future efforts to integrate the behavioral and social sciences in interdisciplinary health research?

APPROACH: Is the need for an interdisciplinary approach to advance the science in the chosen health research topic area justified? Will the proposed methodological innovation(s) advance the specific interdisciplinary research goals and objectives in the chosen health topic area? The feasibility of accomplishing the stated objectives and proposed products through the proposed venues and agendas will be review criteria, as will the plans for inclusion of women, minorities and persons with disabilities in the planning, organization, and implementation of the proposed meeting(s) or network.

INNOVATION: Does the proposed methodological development employ novel concepts or approaches? Will it challenge existing paradigms or allow for new research designs, measurement, data collection or analysis? Does the meeting/network employ novel approaches or methods to fulfill its purpose?

INVESTIGATOR: Is the principal investigator appropriately trained and well suited to the project? Is the proposed project appropriate to the experience level of the principal investigator and other participants and do they have a strong commitment to interdisciplinary research?

ENVIRONMENT: How appropriate is the meeting/network site? Does the applicant organization have the ability to contribute to the probability of success? Do the proposed meetings, exhibits, interactions, etc., take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score.

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for

the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed meeting(s) or network.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: March 26, 2004
Application Receipt Date: April 26, 2004
Peer Review Date: June/July 2004
Council or Advisory Board Review: September 2004
Earliest Anticipated Start Date: September 30, 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit (as determined by peer review);
o Availability of funds; and
o Programmatic priorities.

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
See http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

All investigators proposing conferences and workshops should read the “NIH Guidelines for Inclusion of Women, Minorities, and Persons with Disabilities in NIH-Supported Conference Grants.” A complete copy of the updated guidelines is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under 21 years of age) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy

Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.healthypeople.gov/.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284)and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index

Return to NIH Guide Main Index

Department of Health and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892